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EXAMINER	
MCMILLIAN, KARA RENITA	
ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/602,129	SHEPARD, SCOT R.	
	Examiner	Art Unit	
	KARA R. MCMILLIAN	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,12,16-20 and 25-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,12,16-20 and 25-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendments filed January 7, 2010 amending claims 10, 18, 25, 30 and adding new claims 35-37 have been entered. Claims 1-9, 11, 13-15 and 21-24 were previously canceled. Claims 10, 12, 16-20 and 25-37 are currently pending and presented for examination.

Response to Arguments

Due to Applicants amendment of claim 18, the previous rejection of claims 18-20 under 35 USC 102 over Birnie et al. has been withdrawn. Applicant's arguments filed January 7, 2010 in response to the rejection of claims 18-20 under 35 USC 102 over Birnie et al. have been fully considered but they are moot in view of the withdrawal of the rejection. However, a new rejection under 35 USC 103 is detailed below because although claim 18 has been amended to recite that the agent is a viral agent and the biological source material comprises a biomolecule of interest, Birnie et al. teach that betaines and amine oxides are two types of amphoteric surfactants that have each been shown to exhibit antimicrobial activity against a variety of microorganisms (page 2514). Birnie et al. further teach that although each of these compounds has shown pronounced activity alone, they have also been used in combination to exhibit a synergistic effect (page 2514). Birnie et al. further teach that equimolar mixtures of N-alkyl betaine and N-alkyl-N,N-dimethylamine oxide with chain lengths ranging from C_8 to

C_{18} have been shown to have pronounced activity not only against bacteria, but also against yeasts, fungi, sperm and enveloped viruses (page 2514). Thus Birnie et al. teach that amine oxides have antimicrobial activity including antibacterial as well as antiviral.

Furthermore, claim 18 of the instant application claims contacting the biological source material, wherein the biological source material comprises a biomolecule of interest. In the instant specification, Applicants define a biological source material as being a host cell, wherein a host cell can be a cell of any type such as a bacterial cell and the biomolecule of interest is protein, lipid, etc. Birnie et al. teach contacting bacterial cells with N-alkyl-N,N-dimethylamine oxide (C8 to C18) (see page 2515). Thus since bacteria contain biomolecules of interest such as proteins, lipids, etc., Birnie et al. teach contacting a biological source material comprising a biomolecule of interest.

Applicant's arguments filed January 7, 2010 in response to the rejection under 35 USC 103 over Fonsny et al. in view of Rasmussen et al. have been fully considered but they are not persuasive. Applicants argue that Fonsny et al. relate to a stable cleaning composition formulated for cleaning hard surfaces and as such Fonsny et al. do not teach or suggest a method for using specific alkyl amines or amine oxides for inactivation viral agents in a biological source material such as a host cell, cell supernatant, etc. which comprises a biomolecule of interest.

This argument is found not persuasive since Fonsny et al. teach compositions for disinfecting surfaces using amines or amine oxides. Thus to a person of ordinary skill in the art, a surface which is in need of disinfection is one that comprises microbial agents

such as bacteria, viruses, yeast, fungi, etc. Thus, since Fonsny et al. broadly teach a composition that is effective in disinfecting a surface, inactivating all microbial agents including viruses is contemplated. Furthermore, since Fonsny et al. teach a composition for disinfecting surfaces, it would be obvious to use said composition to clean and disinfect surfaces contaminated with bodily fluids such as blood or feces which are contaminated with bacteria, viruses, yeast, fungi, etc. For example, since Fonsny et al. teach a disinfectant composition, it would be obvious to a person of ordinary skill in the art to use said composition in a hospital setting to clean and disinfect substances which have come in contact with a patient's bodily fluids such as urine, feces, blood, etc. Therefore, since the composition will come in contact with blood that contains cells that contain proteins, claim 10 of the instant application is rendered obvious.

Applicants further argue that Fonsny et al. do not teach inactivating viral agents in a biological source material without damaging the biomolecule of interest. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., without damaging the biomolecule of interest) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, Applicants argue that there was a need for a gentle, non-denaturative method for reducing unwanted viral activity without damaging the desired

molecules or substances of interest and the presently claimed invention provides such a method. This argument is found not persuasive because as stated above although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims, therefore as presently written the instant claims are rendered obvious by the recited prior art references.

Applicants further argue that Rasmussen et al. do not cure the deficiencies of Fonsny et al. This argument is found not persuasive based on the rationale presented above.

Applicant's arguments filed January 7, 2010 with respect to the rejections under 35 USC § 103 over Michaels have been fully considered but they are not persuasive.

Applicants argue that Michaels relates to antiinfective water in oil and oil in water emulsions than can be used in cleansers, lotions, ointments, etc. that exhibit antiinfective activity and Michaels does not teach or suggest a method for using specific alky amines or amine oxides for inactivating viral agents in a biological source material such as a host cell, cell supernatant, etc. which comprises a biomolecule of interest.

This argument is found not persuasive since Michaels teaches compositions containing amine oxides such as decyl-N,N-dimethylamine oxide which are less irritating to mammalian tissues or cells for the purpose of cleaning and disinfecting (column 2 lines 30-33). Michaels further teach compositions of surfactant formulations which can be used for antiinfective or disinfection purposes for longer periods of time than other previously known compositions containing betaines and amine oxides (column 2 lines 34-39). Thus Michaels teaches using a composition comprising amine

oxides to disinfect mammalian skin to aid in wound healing and treat damaged skin without irritating mammalian tissues or cells (column 2 lines 40-43). Michaels therefore teaches contacting mammalian tissues and cells (biological source material) which obviously contain proteins (biomolecule of interest). Furthermore, since Michaels broadly teaches that the composition can be used as a disinfectant, and a disinfectant is active against all microbes including bacteria, viruses, yeast, fungi, etc., inactivation of all microbial agents including viruses are contemplated. Thus inactivation of a viral agent is rendered obvious in view of Michaels.

Applicants further argue that Michaels fails to teach or suggest that a method for using specific alkyl amines or amine oxides for inactivating a viral agent without damaging the biomolecule of interest. This argument is found not persuasive since Applicants are arguing limitations that are not present in the claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. without damaging the biomolecule of interest) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was

within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

For the reasons of record and for the reasons presented above the previous rejections are maintained however modified rejections necessitated by applicants' amendments are detailed below. Accordingly this action is made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birnie et al. (Antimicrobial Evaluation of N-Alkyl Betaines and N-Alkyl-N,N-dimethylamine Oxides with Variations in Chain Length, Sept. 2000, Antimicrobial Agents and Chemotherapy, Vol. 44, No. 9, pp. 2514-2517).

Claims 18-20 of the instant application claim a method of inactivating a viral agent in a biological source material which contains a biomolecule of interest, comprising contacting the biological source material with a solution consisting

essentially of an effective amount of an amine oxide, wherein the amine oxide is selected from the group consisting of: dimethyldecylamineoxide, dimethylundecylamineoxide, dimethyldidecylamineoxide and dimethyltridecylamineoxide.

The examiner respectfully points out that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

Birnie et al. teach, in the abstract of page 2514, that alkyl betaines and alkyl dimethylamine oxides have been shown to have pronounced antimicrobial activity when used individually or in combination. Birnie et al. teach that betaines and amine oxides are two types of amphoteric surfactants that have each been shown to exhibit antimicrobial activity against a variety of microorganisms (page 2514). Birnie et al. further teach that although each of these compounds has shown pronounced activity alone, they have also been used in combination to exhibit a synergistic effect (page 2514). Birnie et al. further teach that equimolar mixtures of N-alkyl betaine and N-alkyl-N,N-dimethylamine oxide with chain lengths ranging from C_8 to C_{18} have been shown to have pronounced activity not only against bacteria, but also against yeasts, fungi, sperm and enveloped viruses (page 2514). Thus Birnie et al. teach that amine oxides have antimicrobial activity including antibacterial as well as antiviral.

In Table 3 on page 2515, Birnie et al. show the activity of N-alkyl-N,N,-dimethylamine oxides against the bacteria *S. aureus* and *E. coli* as a function of alkyl chain length. Table 3 clearly indicates that N-alkyl-N,N-dimethylamine oxides have antimicrobial activity, including the amine oxides currently claimed. Specifically claims 18-20 of the instant application claim dimethyldecylaminoxide which is equivalent to C_{10} amine oxide and dimethyldidecylamineoxide which is equivalent to C_{12} amine oxide (see Table 3 page 2515). Thus Birnie et al. teach contacting bacteria cells with amine oxides.

Birnie et al. also teach effective concentrations of N-alkyl-N, N-dimethylamine oxide within the range claimed in the instant application (see Table 3 on page 2515).

Birnie et al. do not specifically teach inactivating a viral agent in a biological source material.

In the instant specification, Applicants define a biological source material as being a host cell, wherein a host cell can be a cell of any type such as a bacterial cell and the biomolecule of interest is protein, lipid, etc. Birnie et al. teach contacting bacterial cells with N-alkyl-N,N-dimethylamine oxide (C_8 to C_{18}) (see page 2515). Thus since bacteria contain biomolecules of interest such as proteins, lipids, etc., Birnie et al. teach contacting a biological source material comprising a biomolecule of interest.

Furthermore since Birnie et al. teach that the amine oxides have pronounced activity against enveloped viruses, it would be obvious to a person of ordinary skill in the art that the amine oxide would also inactivate any enveloped virus associated with the bacteria cells. Thus claims 18-20 of the instant application are rendered obvious.

Claims 10, 12, 16-20 and 25-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonsny et al. U.S. Patent No. 5,911,915 in view of Rasmussen et al. Publication No. US 2002/0022649 A1.

Claims 10, 12, 16, 17 and 35-37 of the instant application claim a method of inactivating a viral agent in a biological source material such as a mammalian cell, comprising contacting the biological source material which comprises a biomolecule of interest such as a protein with a solution comprising an effective amount of an amine, wherein the amine is selected from the group consisting of: dimethyldecylamine,

dimethyltridecylamine, dimethylundecylamine, dimethyldidecylamine, dimethyltetradecylamine, and dimethylhexadecylamine. Claims 18-20 of the instant application claim a method of inactivating a viral agent in a biological source material, comprising contacting the biological source material with a solution consisting essentially of an effective amount of an amine oxide, wherein the amine oxide is selected from the group consisting of: dimethyldecylamineoxide, dimethylundecylamineoxide, dimethyldidecylamineoxide and dimethyltridecylamineoxide. Claims 25-29 of the instant application also claim the method of claims 18-20 wherein the solution consists essentially of a polyol and an amine oxide. Claims 30-34 of the instant application claims the method of claims 10, 12, 16 and 17 wherein the solution consists essentially of a polyol and an amine.

The examiner respectfully points out that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing

intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language.").

Fonsny et al. disclose a stable, clear, multipurpose, hard surface cleaning composition especially effective in disinfecting the surface being cleaned (see column 2 lines 19-21). The composition disclosed by Fonsny et al. comprises among other ingredients, 0.1% to 20% of a nonionic surfactant and/or an ethoxylated glycerol type compound, 0.1% to 20% of at least one disinfecting agent such as a cationic surfactant, and 0.1% to 20% of an amphoteric surfactant (see column 2 lines 47-58). Fonsny et al. further disclose that the compositions contain preferably 0.25% to 8% of a disinfectant agent selected from C_8-C_{16} alkyl amines, and that amine oxides can be optionally used at a concentration of 0 to 10%, more preferably 0.1% to 8% (see column 8 lines 45-67). Fonsny et al. further disclose in column 9 lines 1-13 the formula of suitable amine oxides which can be any one of the amine oxides claimed in claims 18 and 25 of the instant application.

Fonsny et al. do not specifically teach inactivating a viral agent. Fonsny et al. do not specifically teach contacting a biological source material (a mammalian cell) which comprises a biomolecule of interest (a protein). Fonsny et al. do not specifically exemplify the amines and amine oxides as claimed in the instant invention. Fonsny et

al. do not specifically teach the exact ranges of each of the components claimed in the instant application. Fonsny et al. do not specifically disclose the inclusion of glycerol in the disinfectant composition.

Fonsny et al. teach compositions for disinfecting surfaces using amines or amine oxides. Thus to a person of ordinary skill in the art, a surface which is in need of disinfection is one that comprises microbial agents such as bacteria, viruses, yeast, fungi, etc. Thus, since Fonsny et al. broadly teach a composition that is effective in disinfecting a surface, inactivating all microbial agents including viruses is contemplated. Furthermore, since Fonsny et al. teach a composition for disinfecting surfaces, it would be obvious to use said composition to clean and disinfect surfaces contaminated with bodily fluids such as blood or feces which are contaminated with bacteria, viruses, yeast, fungi, etc. For example, since Fonsny et al. teach a disinfectant composition, it would be obvious to a person of ordinary skill in the art to use said composition in a hospital setting to clean and disinfect substances which have come in contact with a patient's bodily fluids such as urine, feces, blood, etc. Therefore, since the composition will come in contact with blood that contains cells that contain proteins, a method of inactivating a viral agent in a biological source material that comprises a biomolecule of interest is rendered obvious.

Fonsny et al. broadly disclose C_8-C_{16} alkyl amines and C_{10}-C_{18} alkyl amine oxides useful as disinfectants which renders the amines and amine oxides claimed in the instant application obvious (see column 8 line 45 to column 9 lines 14).

Fonsny et al. disclose ranges of each of the components claimed in the instant application that overlap with the ranges claimed in the instant application. Fonsny et al. teach 0.1% to 8% of C8-C16 alkyl amines (column 8 lines 45-48) and 0 to 10% of an amine oxide (column 8 lines 65-67).

Fonsny et al. disclose the use of 0.1% to 20% of a nonionic surfactant and/or an ethoxylated glycerol type compound (see column 2 lines 49-50).

Rasmussen et al. teach in paragraph [0075] that glycerol is a nonionic surfactant.

Accordingly, one of ordinary skill in the art at the time of the instant invention would have found it obvious to combine the teachings of Fonsny et al., which teach the use of 0.1% to 20% of a nonionic surfactant in a disinfectant composition with the teachings of Rasmussen et al. which teach that glycerol is a nonionic surfactant. Thus, since the composition of Fonsny et al. calls for the inclusion of a nonionic surfactant, and glycerol is a known nonionic surfactant (as disclosed by Rasmussen et al.) one of ordinary skill in the art would be motivated to include glycerol in the composition disclosed by Fonsny with a reasonable expectation of similar success in providing a disinfectant composition.

Regarding claim 16, it would be obvious to an ordinary skilled artisan that any composition that contains surfactants such as those disclosed in the compositions of Fonsny et al. would lyse cells. Thus claim 16 is also rendered obvious by Fonsny et al.

In conclusion claims 10, 12, 16-20 and 25-37 of the instant application are rendered obvious by Fonsny et al. in view of Rasmussen et al. since Fonsny et al.

disclose disinfectant compositions comprising amines or amine oxides and Rasmussen et al. renders obvious the inclusion of glycerol in the composition.

Claims 18-20 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michaels, U.S. Patent No. 5,389,676.

Claims 18-20 of the instant application claim a method of inactivating a viral agent in a biological source material which comprises a biomolecule of interest, comprising contacting the biological source material with a solution consisting essentially of an effective amount of an amine oxide, wherein the amine oxide is selected from the group consisting of: dimethyldecylamineoxide, dimethylundecylamineoxide, dimethyldidecylamineoxide and dimethyltridecylamineoxide. Claims 25-29 of the instant application also claim the method of claims 18-20 wherein the solution consists essentially of a polyol and an amine oxide.

The examiner respectfully points out that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re

De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language.").

Michaels teaches, in column 2 lines 20-45 compositions comprising surfactants including amine oxides with increased viscosity for use in the formulation of disinfectants. The compositions can be used in the treatment of mammalian tissue or cells (which contain protein which is a biomolecule of interest) with less irritation than the usual surfactants used for cleaning and disinfecting. Michaels further teaches that the surfactants useful as disinfectants and can be used in the treatment of damaged skin. Michaels discloses in column 3 line 63 through column 4 line 3 examples of amine oxides including decyl-N,N-dimethylamine oxide (equivalent to the dimethyldecylamineoxide).

Michaels teaches in column 5 lines 38-57 that preferred compositions contain 0.1-10% of the active ingredient one of which is the amine oxide. Michaels further teaches, in col. 10 lines 20-60, zone of inhibition tests against bacteria S. sanguis M5

performed using a composition comprising 0.5% of C31G (a 1:1 betaine to amine oxide composition), and 5% glycerin (equivalent to glycerol).

Michaels does not specifically exemplify a composition comprising one of the amine oxides claimed in claims 18 and 25 of the instant application. Michaels does not specifically teach inactivating a viral agent.

Michaels does disclose that decyl-N,N-dimethylamine oxide (equivalent to the dimethyldecylamineoxide) is an example of an amine oxide useful in the anti-infective or disinfectant composition (see column 3 lines 63-64). Michaels discloses numerous amine oxides useful in the anti-infective or disinfectant composition. As such, an ordinary skilled artisan would be motivated to use any of the amine oxides listed in Michaels (see column 3 line 63- column 4 lines 3) including dimethyldecylamineoxide with a reasonable expectation of similar success.

Michaels teaches compositions of surfactant formulations which can be used for antiinfective or disinfection purposes for longer periods of time than other previously known compositions containing betaines and amine oxides (column 2 lines 34-39). Michaels teaches using a composition comprising amine oxides to disinfect mammalian skin to aid in wound healing and treat damaged skin without irritating mammalian tissues or cells (column 2 lines 40-43). Michaels therefore teaches contacting mammalian tissues and cells (biological source material) which obviously contain proteins (biomolecule of interest). Furthermore, since Michaels broadly teaches that the composition can be used as a disinfectant, and a disinfectant is active against all microbes including bacteria, viruses, yeast, fungi, etc., inactivation of all microbial

agents including viruses are contemplated. Thus inactivation of a viral agent is rendered obvious in view of Michaels.

As such claims 18-20 and 25-29 are rendered obvious in view of the teachings of Michaels.

Conclusions

Claims 10, 12, 16-20 and 25-37 are rejected. Claims 1-9, 11, 13-15 and 21-24 are cancelled. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA R. MCMILLIAN whose telephone number is

(571)270-5236. The examiner can normally be reached on Monday-Thursday from 8:30 am- 6:00 pm and every other Friday from 8:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kara R. McMillian/
Examiner, Art Unit 1627

KRM

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627